

MAR 22 2002

PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE
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(use as many sheets as necessary)

Sheet	1	Of	4	Attorney Docket No.	96-223-ZZ
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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear
		Number	Kind Code ² (if known)			
SUL	1	5,106,833		Bronze, Jr. et al.	04-21-1992	
	2	5,223,482		Schilling, Jr. et al.	07-29-1993	
	3	5,312,736		Rasmussen et al.	05-17-1994	
	4	5,403,484		Ladner et al.	04-04-1995	
	5	5,407,915		Fritz et al.	04-18-1995	
	6	5,436,153		Sprecher et al.	07-25-1995	
	7	5,441,931		Sprecher et al.	08-08-1995	
	8	5,541,288		Nakano et al.	07-30-1996	
	9	5,576,294		Norris et al.	11-19-1996	
	10	5,663,143		Ley et al.	09-02-1997	
	11	5,677,146		Sprecher et al.	10-14-1997	
	12	5,728,674		Sprecher et al.	03-17-1998	
	13	5,731,412		Shimomura	03-24-1998	
	14	5,736,364		Kelley et al.	04-07-1998	
	15	5,747,449		Lasters et al.	05-05-1998	
	16	5,786,328		Dennis et al.	07-28-1998	
	17	5,795,865		Markland et al.	08-18-1998	
	18	5,834,244		Dennis et al.	11-10-1998	
SUL	19	5,854,396		Shimomura et al.	12-29-1998	

Examiner Signature	<i>Sacchetti</i>	Date Considered	6-15-04
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English translation is attached.

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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear	T ²
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
SWL	20	EP	0 439 442	B1	Washington Univ.	03-06-96	
	21	EP	0 563 389	A1	Zhurnov, Oleg Petrovich	10-06-93	
	22	EP	0 758 682	A2	Mitsubishi Chemical Corp.	02-19-97	
	23	WO	92/15605	A2	Protein Engineering Corp.	09-17-92	
	24	WO	93/14120	A1	Novo Nordisk A/S	07-22-93	
	25	WO	95/18830	A2	Protein Engineering Corp.	07-13-95	
	26	WO	96/03503	A1	The Green Cross Corp.	02-26-97	
	27	WO	96/35788	A2	Scios, Inc.	11-14-96	
	28	WO	97/33996	A2	Bayer Corp.	09-18-97	
SWL	29	WO	98/33920	A2	Human Genome Sciences, Inc.	08-06-98	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
SWL	30	APP, E.M., KING, M., HELFESRIEDER, R., KOHLER, D., AND MATTHYS, H. (1990) Acute and long-term amiloride inhalation in cystic fibrosis lung disease. A rational approach to cystic fibrosis therapy. <i>American Review of Respiratory Disease</i> 141, 605-612.	
	31	CHRAIBI, A., VALLET, V., FIRSOV, D., HESS, S.K., AND HORISBERGER, J.D. Protease modulation of the activity of the epithelial sodium channel expressed in xenopus oocytes. <i>Journal of General Physiology</i> 111(1): 127-138, 1998.	
	32	DELARIA, K.A., MULLER, D.K., MARLOR, C.W., BROWN, J.E., DAS, R.C., ROCZNAK, S.O. AND TAMBURINI, P.P. Characterization of placental bikunin, a novel serine protease inhibitor. <i>Journal of Biological Chemistry</i> 272(18):12209-12214, 1997.	
	33	DENDA, K. Genbank accession no. AB006534. "Homo sapiens mRNA for hepatocyte growth factor activator inhibitor type 2, complete cds." 04-Mar-1998.	
	34	DIETRICH, W. et al. (1989) Thorac. Cardiovasc. Surg. 37:92-98.	
	35	HILLIER, L. et al. EMBL/Genbank accession no. N39798. "The WashU-Merck EST Project." January 26, 1996.	
	36	HILLIER, L. et al. EMBL/Genbank accession no. R35464. "The WashU-Merck EST Project." May 4, 1995.	
	37	HILLIER, L. et al. EMBL/Genbank accession no. R74593. "The WashU-Merck EST Project." June 9, 1995.	
SWL	38	KAWAGUCHI, T., QIN, L., SHIMOMURA, T., KONDO, J., MATSUMOTO, K. DENDA, K., AND KITAMURA, N. (1997) "Purification and cloning of hepatocyte growth factor activator inhibitor type 2, a kunitz-type serine protease inhibitor" J. Biol. Chem. 272:27558-27564.	

Examiner Signature	<i>SWL</i>	Date Considered	6-15-04
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS, CONT.			
Examiner Initials	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
SJL	39	LINDBERG, S., AND OLSSON, H., 1991 "Tissue Kallikrein Stimulates Mucociliary Activity in the Rabbit Maxillary Sinus," <i>Acta Oto-Laryngologica</i> , 111, (6) pp. 1126 – 1132.	
	40	MARLOR, C.W., DELARIA, K.A., DAVIS, G., MULLER, D.K., GREVE, J.M., AND TAMBURINI, P.P. Identification and cloning of human placental bikunin, a novel serine protease inhibitor containing two kunitz domains. <i>Journal of Biological Chemistry</i> 272(18):12202-12208, 1997.	
	41	MATHEWS, L.W., SPECTOR, S., LEMM, J., AND POTTER, J.L. Studies on Pulmonary secretions. I. The Overall Chemical Composition of Pulmonary Secretions from Patients with Cystic Fibrosis, Bronchiectasis, and Laryngectomy. <i>American Review of Respiratory Disease</i> 88:199-204, 1963.	
	42	MCAULAY, A.E., CROSSLEY, J., PLACE, G.A. AND POLL, C.T. Effect of UTP on ion transport in tertiary cultures of human bronchial epithelial (HBE) cells. <i>Pediatric Pulmonology</i> S 17, Abs 141, 1998.	
	43	MIYAZAWA, K. et al. (1996) "Activation of hepatocyte growth factor in the injured tissues is mediated by hepatocyte growth factor activator" <i>J. Biol. Chem.</i> 271:3615-2618.	
	44	NEWTON, B.B. AND HALL, R.L. Mucociliary clearance in the guinea-pig is increased by ouabain (i.v.) and by hypertonic saline (14.4%) aerosol. In <i>Cilia, Mucus and Mucociliary Interactions</i> . Ed. Baum, G.L., Priel, Z., Roth, Y., Liron, N., Ostfield, E., Marcel Dekker. New York, 1998.	
	45	NEWTON, B.B., POLL, C.T. AND HALL, R.L. Inhalation of amiloride increases tracheal mucus velocity and decreases tracheal potential difference in the guinea-pig. <i>Pediatric Pulmonology</i> S17, Abs 364, 1998.	
	46	O'RIORDAN, T.G., MAO, Y.M., OTERO, R., LOPEZ, J., SABATER, J.R., AND ABRAHAM, W.M. Budesonide affects allergic mucociliary dysfunction. <i>Journal of Applied Physiology</i> 85(3):1086-1091, 1998.	
	47	O'RIORDAN, T.G., OTERO, R., MAO, Y.M., LAUREDO, I., AND ABRAHAM, W.M. Elastase contributes to antigen-induced mucociliary dysfunction in ovine airways. <i>American Journal of Respiratory & Critical Care Medicine</i> 97(5):1522-1528, 1997.	
	48	POTTER, J.L., MATTHEWS, L.W., SPECTOR, S., AND LEMM, J. Studies on pulmonary secretions. II. Osmolality and the ionic environment of pulmonary secretions from patients with cystic fibrosis, bronchiectasis, and laryngectomy. <i>American Review of Respiratory Disease</i> 67(I):83-87, 1967.	
	49	RASCHE, VON B., MARCIC, I., AND ULMER, W.T. , 1975 "Über die Wirkung des Proteaseinhibitors Aprotinin auf die Lungenfunktion sowie die inhibitorische Aktivität des Sputums bei Patientin mit chronisch-obstruktiver Bronchitis" <i>Arzneimittel-Forschung (Drug Res.)</i> 25, Nr.(1) 110-116 .	
	50	ROBINSON, et al., 1997. "Effect of increasing doses of hypertonic saline on mucociliary clearance in patients with cystic fibrosis," pp. 900.	
	51	ROBINSON, M., HEMMING, A.L., REGNIS, J.A., WONG, A.G., BAILEY, D.L., BAUTOVICH, G.J., KING, M., AND BYE, P.T.P. Effect of increasing doses of hypertonic saline on mucociliary clearance in patients with cystic fibrosis. <i>Thorax</i> 52(10):900-903, 1997.	
	52	SCHMIDT, O.P., 1977, "Medikamentöse Therapie bronchosekretorischer Störungen" <i>Medizinische Klinik</i> . 72 (5), 145-160.	
	53	SHIMOMURA, T. et al. (1997) "Hepatocyte growth factor activator inhibitor, a novel kunitz-type serine protease inhibitor" <i>J. Biol. Chem.</i> 272:6370-6376.	
	54	TOMKIEWICZ, R.P., APP, E.M., ZAYAS, J.G., RAMIREZ, O., CHURCH, N., BOUCHER, R.C., KNOWLES, M.R., AND KING, M. Amiloride inhalation therapy in cystic fibrosis. Influence on ion content, hydration, and rheology of sputum. <i>American Review of Respiratory Disease</i> 148(4 Pt 1):1002-1007, 1993.	
	55	VALLET, V., CHRAIBI, A., GAEGELE, H.P., HORISBERGER, J.D., AND ROSSIER, B.C. An epithelial serine protease activates the amiloride-sensitive sodium channel. <i>Nature</i> 389(6651):607-610, 1997.	
	56	WILLS, P.J., GARCIA SUAREZ, M.J., RUTMAN, A., WILSON, R., AND COLE, P.J. The ciliary transportability of sputum is slow on the mucus-depleted bovine trachea. <i>American Journal of Respiratory & Critical Care Medicine</i> 151(4):1255-1258, 1995.	
SJL	57	WILLS, P.J., HALL, R.L., CHAN, W.M., AND COLE, P.J. Sodium chloride increases the ciliary transportability of cystic fibrosis and bronchiectasis sputum on the mucus-depleted bovine trachea. <i>Journal of Clinical Investigation</i> 97(11):9-13, 1997.	

Examiner Signature	SJL	Date Considered	6-15-04
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS, CONT.

JULY 4	58	WOJTA et al. (1994) "Hepatocyte growth factor stimulates expression of plasminogen activator inhibitor type 1 and tissue factor in HepG2 cells" Blood 84:151-157 (Abstract).	
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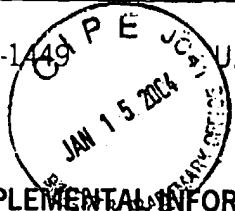


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		6-15-04

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STATEMENT BY APPLICANT

Atty. Docket No.

96-223-ZZ

Serial No.

09/974,026

Applicant: P. Tamburini, et al.

Filing Date:
October 10, 2001

Group: 1653

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No

OTHER DOCUMENTS - Including Author, Title, Date, Pertinent Pages, Etc.

SWL	1.	Gribben et al. (1990), "Development of antibodies to unprotected glycosylation sites on recombinant human GM-CSF", The Lancet 335:434-437.
	2.	Hotchkiss et al. (1988), "The Influence of Carbohydrate Structure on the Clearance of Recombinant Tissue-Type Plasminogen Activator", Thrombosis and Haemostasis 60 (2):255-261.
	3.	Petersen et al. (1996), "Inhibitory properties of separate recombinant Kunitz-type-protease-inhibitor domains from tissue-factor-pathway inhibitor", Eur. J. Biochem. 235:310-316.
	4.	Hochstrasser et al. (1981), "Kunitz-Type Proteinase Inhibitor Derived by Limited Proteolysis of the Inter-Trypsin Inhibitor", Hoppe-Seyler's Z. Physiol. Chem. 362:1357-1362.
SWL	5.	Yuki et al. (1993), "Charge isomers of urinary bikunin (trypsin inhibitor)", Biochimica et Biophysica Acta.1203:298-303.

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Date Considered

6-15-04